Real-world Evidence on Diagnosed Gastroparesis in Europe: Multi-database Observational Epidemiological Study (TAK-906-5003)

First published: 19/02/2021

Last updated: 25/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49349

EU PAS number

EUPAS37806

Study ID

49349

DARWIN EU® study

No

Study countries

☐ Finland

☐ Spain

Study description

The study will provide information about people with gastroparesis.

The main aims are to estimate the number of new cases of gastroparesis during a specific time and to estimate the total number of cases of gastroparesis.

Cases of gastroparesis will be found from records held in large healthcare databases, based on information on diagnoses, test results, and treatment for the condition.

Children, teenagers, and adults will be included in the study.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

☐ United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

Fabian Hoti

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Fabian Hoti

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/06/2019

Actual: 12/06/2019

Study start date

Planned: 22/02/2021

Actual: 25/02/2021

Date of final study report

Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To assess the incidence and prevalence of gastroparesis in the populations in countries of interest and to describe patients with gastroparesis in terms of

their characteristics incl. socio-demographic characteristics, etiologic factors, clinical characteristics, diagnostic and treatment practices.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Impaired gastric emptying

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

9000000

Study design details

Outcomes

The primary outcome for the analyses of incidence and prevalence will be gastroparesis, as identified using a case definition based on information on diagnoses and other clinical records, records of conducted tests and test results, procedures, and recorded pharmacological and non-pharmacological treatment.

Data analysis plan

Cases of gastroparesis will be identified using a case definition based on information on diagnoses and other clinical records, records of conducted tests and test results, procedures, and recorded pharmacological and non-pharmacological treatment.

For the analyses of occurrence of gastroparesis, the incidence rate and prevalence with 95% confidence intervals will be estimated. Incidence rates and prevalence will be reported overall and stratified by age group, sex, and calendar year.

For the analyses of characteristics of cases of gastroparesis, standard descriptive statistical method measures will be used, including mean, standard deviation, median, and distribution quartiles, number of non-missing observations, number of participants with missing data.

For categorical variables, the proportion and frequency of patients in each category level will be reported.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No